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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,024	10/31/2001	Shuk-Mei Ho	07917-110001 / (UMMC 00-2	7825

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,024	HO ET AL.	
	Examin r	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication app ars on the c v r she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-VII. Claims 1-12, drawn to methods of using SEQ ID NOS: 1-7 respectively, said methods drawn to inducing apoptosis in a human cancer cell, the method of each group comprising introducing into the cell one of the above ribozymes, or vectors thereto, classified in class 514, subclass 44.

VIII-XIV. Claims 13-19, drawn to methods of using SEQ ID NOS: 1-7 respectively, said methods drawn to inhibiting growth of a tumor, the method comprising introducing into cells of the tumor one of the above ribozymes or vectors thereto, classified in class 514, subclass 44.

XV-XXI. Claims 20-33, drawn to methods of using SEQ ID NOS: 1-7 respectively, said methods drawn to enhancing the effectiveness of cancer therapy, the method comprising introducing into cancer cells of a patient a ribozyme or vector thereto that inhibits metallothionein expression, and administering to the patient a therapeutically effective amount of a cancer therapy agent, classified in class 514, subclass 44.

XXII-XXVII. Claims 34-38, drawn to a ribozyme of SEQ ID NOS: 1-7 respectively, and vectors thereof, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the ribozyme sequences listed in the instant claims are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

The Group of each of the Group sets listed above specifically claim ribozyme SEQ ID NOS 1-7, or uses thereof, which are targeted to and modulates the expression of metallothionein. Although the ribozyme sequences claimed each target and modulate different isoforms of the same gene, the instant ribozyme sequences are considered to be unrelated, since each ribozyme sequence claimed is structurally and functionally independent and distinct for the following reasons: each ribozyme sequence has a unique nucleotide sequence, each ribozyme sequence targets a different and specific region of metallothionein, and each ribozyme, upon binding to metallothionein, functionally modulates (increases or decreases) the expression of the gene and to varying degree. Furthermore, a search of more than one (1) of the ribozyme sequences claimed in the instant application presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed ribozyme sequences. In view of the foregoing, one (1) ribozyme sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one Group containing one (1) ribozyme sequence.

The method of Groups I-VII are unrelated to those of any other Group. Similarly, the method of Groups VIII-XIV are unrelated to those of any other, and the method of Groups XV-

XXI are unrelated to those of any other, Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related, because none of the inventions have been disclosed as being used together, and further because the methods above have different effects and modes of operation. For example, the method of Groups I-VII, drawn to the use of ribozymes to induce apoptosis, require tests to determine whether or not apoptosis has occurred, which are steps and effects that not found in any other Group. The method of Groups I-VII, drawn to the use of ribozymes to inhibit the growth of a tumor comprising introducing a ribozyme into cells of the tumor, requires the identification and delivery of ribozymes into a tumor, and verification that tumor growth was inhibited, which are steps and outcomes unique to this grouping. Finally, the method of Groups XV-XXI, drawn to the treatment of cancer comprising administering both the ribozyme and anti-cancer drugs, involves patient diagnosis, administration of drugs, and verification that treatment effects have occurred, steps not found any other claimed method.

Finally, the inventions of Groups XXII-XXVIII and Groups I-XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ribozymes may be used in an *in vitro* method of target inhibition to determine gene function.

Furthermore, a search of all such inventions presents an undue burden on the Patent Office, because a search for art against one group does not return search for art against the other. Accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD

Karen Lacourciere

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER